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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/580,819	05/26/2000	Vadim Vladimirovich Yuzhakov	7606R	9337

27752 7590 05/09/2003

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EXAMINER

DESANTO, MATTHEW F

ART UNIT PAPER NUMBER

3763

DATE MAILED: 05/09/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/580,819

Applicant(s)

YUZHAKOV ET AL.

Examiner

Matthew F DeSanto

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 12 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 8-12, 20 and 24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 13-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2/3 9/10
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Election/Restrictions***

1. Applicant's election with traverse of Species A and sub-species of hollow microneedles in Paper No. 10 is acknowledged. The traversal is on the ground(s) that the independent claims covers all the forms of the microneedles. This is not found persuasive because, this would be the argument that claim 1 is generic and therefore there is no argument for whether the restriction is proper. According to the MPEP section 800 since there are different embodiments as stated on page 14 of the specification, the examiner still feels the restriction is proper.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 8-12 and 20-24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 10.

***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-4, 6, 13-17, and 18 are rejected under 35 U.S.C. 102(e) as being anticipated by Allen et al. (USPN 6334856).

Allen et al. discloses a microneedle array comprising a plurality of microneedles with a plurality of projections which extend from the second side of said base element and wherein said projections are spaced by a range of 50-1000 micron and wherein said length of projections are 50-3000 micron. (Figures 1A, 1B, 3G, 4D, and Entire reference)

5. Claims 1, 13, are rejected under 35 U.S.C. 102(b) as being anticipated by Gerstel et al. (USPN 3964482).

Gerstel et al. discloses a microneedle array comprising a plurality of microneedles with a plurality of projections which extend from the second side of said base element and wherein said projections are spaced by a range of 50-1000 micron and wherein said length of projections are 50-3000 micron. (Figures 1, 2, 6, and entire reference)

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-7 and 13-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allen et al. as applied above, and further in view of Reed et al. (USPN 5676850).

Allen et al. disclosed the claimed invention except for the hollow element having at least two sharp projections proximal to an end of the hollow element.


Reed et al. disclosed an hollow elements each exhibit an edged outer contour, in a transverse plane, that is perpendicular to a longitudinal axis of said hollow element, said outer contour having at least 2 shape projections (Figure 7, 13 and entire reference)

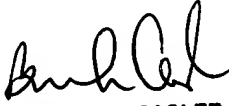
At the time of the invention it would have been obvious for one of ordinary skill in the art to combine the device of Allen et al. with the teachings of Reed et al. because Reed et al. discloses a more efficient way to pierce and directly attach the needles to the organ (Column 5, lines 5-33).

Therefore, it would have been obvious to one of ordinary skill in the art to combine Allen et al. with Reed et al. to obtain the invention as specified in claims 1-7 and 13-19.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew F DeSanto whose telephone number is 1-703-305-3292. The examiner can normally be reached on Monday-Friday 8:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 1-703-308-3552.

  
Matthew DeSanto  
Art Unit 3763  
May 5, 2003

  
BRIAN L. CASLER  
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